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6 **UNITED STATES DISTRICT COURT**
7 **FOR THE NORTHERN DISTRICT OF ILLINOIS**
8 **EASTERN DIVISION**

9 BIDI VAPOR, LLC,

10 Plaintiff,

11 v.

12 VAPERZ LLC, OEM PARTNERS, LLC and
13 VAPERZ ENTERPRISE LLC,

14 Defendants.

15 CASE NO.: 21-cv-01430

16 **DECLARATION OF WILLIE J.
17 MCKINNEY IN SUPPORT OF
18 PLAINTIFF'S MOTION FOR A
19 PRELIMINARY INJUNCTION**

DECLARATION OF WILLIE J MCKINNEY

I, Willie J. McKinney, of full age, hereby declare as follows:

1. My name is Willie J. McKinney Ph.D., DABT and I submit this declaration in support of BIDI's motion for a Preliminary Injunction.

2. I have been engaged by Plaintiff to provide an opinion in the matter of Bidi Vapor, LLC v. Vaperz LLC, et al., 1:21-cv-01430 (“Action”), which is pending in the United States District Court for the Northern District of Illinois.

3. I am being compensated at an hourly rate of \$450/hour. My compensation is not contingent on my opinion or the result in the litigation.

4. My resume accompanies this declaration as **Exhibit A**. I am an inhalation toxicologist with over two decades of industry experience conducting research and developing regulatory science strategies for company decisions and engagements with regulators.

5. I served a 3-year term as the tobacco industry representative on the FDA's Tobacco Product Scientific Advisory Committee (TPSAC). The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner of Food and Drugs.

6. Currently, I am leader of McKinney Regulatory Science Advisors, LLC. Before that I was Vice-President of Global Regulatory Affairs at JUUL LabsVice President of Regulatory Sciences and member of the executive leadership team at Altria, a visiting scientist at the Institut fur Biologische Forschung GmbH and an associate research scientist at the Nelson Institute of Environmental Medicine, NYU Medical Center

7. I have been asked to, and have now reviewed the following materials in connection with this Action: (1) a test report commissioned by Plaintiff from Labstat International, Inc. (“Labstat”) designated in the Action as the, a copy of which accompanies Declaration of Niraj Patel in Support of Plaintiff’s Motion for Preliminary Injunction (“First Patel Dec.”) as **Exhibit A** (“Labstat Report¹”); (2) a test report commissioned by Defendants from Shenzhen Alpha Product Testing Co., LTD (“Alpha”)

¹ I currently sit on the board of Labstat; however, I was not in any way involved in the commission of the Labstat Report.

1 which accompanied the Declaration of Manoj Misra, Ph.D (“Misra Dec.”) as **Exhibits** B-C (“Alpha
2 Report”); (3) a test report commissioned by Defendants from Legend Technical Services, Inc.
3 (“Legend”) which accompanies the Declaration of Scott Creekmur (“Creekmur Dec.”) as **Exhibit B**
4 (“Legend Report”); and (4) a test report commissioned from Plaintiff from Enthalpy Analytical, Inc.
5 (“Enthalpy”) attached hereto as **Exhibit B** (“Enthalpy Report”) (the Labstat Report, the Alpha Report(s),
6 the Legend Report and the Enthalpy Report are collectively hereinafter referred to as “Materials”).

7 8. I have been asked to opine on the Materials, including statements made in the Misra Dec.
8 and the Creekmur Dec. and the results of the tests discussed in the Materials.

9 9. My general conclusion after a review of all Materials, which is discussed in more detail
10 below is that while I do not have experience with Alpha that prepared the Alpha Report and therefore
11 cannot speak to their certifications, ability to accurately measure nicotine, and the quality of their data,
12 assuming that the data provided in the Alpha Report is accurate, the data suggest that while the newly
13 manufactured MNGO Sticks (*i.e.*, less than two weeks old) (*see* Misra Dec., Ex. B-C) may have e-liquid
14 nicotine concentrations that are within an acceptable range for an ENDS device (*i.e.*, +/-10%), in light
15 of the data generated by Labstat and Enthalpy in the corresponding Labstat Report and Enthalpy Report,
16 within a very short timeframe (5-6 months), the nicotine in the e-liquid of MNGO Sticks is rapidly
17 degrading such that the labeling on the MNGO Stick does not accurately reflect the actual levels of
18 nicotine in the MNGO Sticks and therefore I would classify the label as false and misleading.

19 10. Again, assuming that the data in the Alpha Report is accurate, my analysis of the Alpha
20 Report confirms that when Alpha measured the nicotine concentration in the e-liquid of MNGO Stick
21 within 1 or 2 weeks after manufacturing, the MNGO Stick nicotine concentration was 8% to 9% less
22 than the nicotine concentration on a standard MNGO Stick product label. I used the measured nicotine
23 concentrations provided by Alpha (Tables 2 & 3 below) for this calculation.

Table 1: Shenzhen Alpha Product Testing Co., Ltd Test Data (Declaration of Manoj Misra Exhibit B)

MNGO Stick Exhibit B	Age of Samples Tested	Label Nicotine Concentration	Measured Nicotine	Specific Gravity (g/mL) (Assumed)	Nicotine Concentration (mg/mL)	% Reduced Nicotine Relative to Label
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			Concentration (mg/g) ²			
MNGO Stick Blueberry Mango	1-2 weeks	60 mg/mL	49.3 mg/g	1.12 g/mL	55.2 mg/mL	8.0%
MNGO Stick Iced Banana	1-2 weeks	60 mg/mL	48.7 mg/g	1.12 g/mL	54.5 mg/mL	9.2%
MNGO Stick Strawberry Mango	1-2 weeks	60 mg/mL	48.9 mg/g	1.12 g/mL	54.8 mg/mL	8.7%

Table 2: Shenzhen Alpha Product Testing Co., Ltd Test Data (Declaration of Manoj Misra Exhibit C)

MNGO Stick Exhibit C	Age of Samples Tested	Label Nicotine Concentration	Measured Nicotine Concentration (mg/g) ²	Specific Gravity (g/mL) (Assumed)	Nicotine Concentration (mg/mL)	% Reduced Nicotine Relative to Label
MNGO Stick Blueberry Mango	1 to 2 weeks	60 mg/mL	49.1 mg/g	1.12 g/mL	55.0 mg/mL	8.3%
MNGO Stick Iced Banana	1 to 2 weeks	60 mg/mL	49.2 mg/g	1.12 g/mL	55.1 mg/mL	8.2%
MNGO Stick Strawberry Mango	1 to 2 weeks	60mg/mL	48.5 mg/g	1.12 g/mL	54.3 mg/mL	9.5%

11. I have experience working with both Labstat and Enthalpy. Both labs are certified and known within the nicotine industry to provide quality data. I reviewed both the Labstat Report and the Enthalpy Report. When Labstat and Enthalpy measured the nicotine concentration in the e-liquid of older MNGO Sticks (estimated to be 5-6 months old), the MNGO Stick nicotine concentration is up to 39% less than the nicotine concentration on the product label (Tables 4 & 5 below).

Table 3: Labstat International, Inc Test Data

MNGO Stick Labstat Data	Age of Tested Sample ³	Label Nicotine Concentration	Specific Gravity (g/mL) (Measured)	Measured Nicotine Concentration (mg/g)	Measure Nicotine Concentration (%)	Nicotine Concentr ation (mg/mL)	Measure Nicotine Concentrat ion (%)	% Reduced Nicotine Relative to Label
MNGO Stick Blueberry Mango	Estimate 5-6 Months	60 mg/mL	1.16	33.8 mg/g	3.38%	39.2 mg/mL	3.92%	34.7%

³ Analysis performed January 21, 2021.

1	MNGO Stick Iced Banana	Estimate 5-6 Months	60 mg/mL	1.15	31.3 mg/g	3.13%	36.3 mg/mL	3.63%	39.5 %
2	MNGO Stick Strawberry Mango	Estimate 5-6 Months	60 mg/mL	1.15	31.5 mg/g	3.15%	36.2 mg/mL	3.62%	39.6 %

5 **Table 4: Enthalpy Analytical., Inc Test Data**

6 MNGO Stick 7 Enthalpy 8 Data	Age of 9 Tested 10 Sample ⁴	Label Nicotine 11 Concentration	Specific 12 Gravity (g/mL) (Measured)	Measured 13 Nicotine Concentration (mg/g)	Nicotine Concentration Weight (%)	Nicotine Concentration (mg/mL)	Nicotine Concentration Volume (%)	% Reduced Nicotine Relative to Label
MNGO Stick Grape Ice	Estimate 5-6 Months	60 mg/mL	1.15 g/mL	31.9 mg/g	3.19%	36.7 mg/mL	3.67%	38.9%
MNGO Stick Iced Banana	Estimate 5-6 Months	60 mg/mL	1.15 g/mL	32.5 mg/g	3.25%	37.4 mg/mL	3.74%	37.7%
MNGO Stick Strawberry Mango	Estimate 5-6 Months	60 mg/mL	1.15 g/mL	32.8 mg/g	3.28%	37.7 mg/mL	3.77%	37.1%

14 12. We assumed that the tested MNGO Stick samples were 5-6 months old based on our
15 historical knowledge of the time it takes for manufactured ENDS (Electronic Nicotine Delivery System)
16 product to reach retail. This is a conservative estimate. If my estimates are correct (which I believe they
17 are), the MNGO Stick is losing nicotine at a rapid rate.

18 13. It appears that the MNGO company is aware of this issue and based on documents
19 provided in Exhibit D, has attempted to set a “Stability End-Point Specification” so that when others
20 measure the nicotine concentration in its products, they can say that their products meet specifications
21 (e.g., +10% to -35%). A “Stability End-Point Specification” of minus 35% of 53 mg/mL (*see Misra*
22 Dec., Ex.D) suggests that the MNGO company is willing to sell or allow to remain on the market, MNGO
23 Sticks that have a nicotine concentration that is 42.5% less than the nicotine concentration listed on the
24 label. Based my experience working at two large companies that sold nicotine containing products (e.g.,
25 e-cigarettes) a stability specification of -35% is not acceptable. Regardless of the reasons for the rapid
26 nicotine loss, it is unlikely that FDA will provide market authorization for a tobacco product whose e-

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28 ⁴ Analysis performed April 16th 2021

1 liquid nicotine concentration is 42.5% (i.e., lowest Stability End Point Specification 34.5 mg/mL) less
2 than the nicotine concentration on the label (i.e., 60 mg/mL).

3 14. We published a study which showed that nicotine can degrade and form toxic chemicals
4 like nicotine-1-N-oxide⁵. In other words, the mixture of chemicals in the MNGO liquid may be forming
5 new chemicals. The new chemicals could cause lung inflammation and asthma. For this reason, FDA is
6 recommending stability studies on ENDS.

7 15. Although the FDA has not stated that the nicotine concentration of ENDS should be
8 within +/-10%, they are concerned that labels that do not accurately reflect the actual levels of nicotine
9 and this inaccuracy may result in increased health risks to the consumer. According to Section 910(c)(2)
10 of the FD&C Act, the FDA is required to issue an order denying a PMTA if it finds the proposed labeling
11 is false or misleading in said regard. and according to Section 910(c)(2) of the FD&C Act, the FDA is
12 required to issue an order denying a PMTA if it finds the proposed labeling is false or misleading in said
13 regard.

14 16. The data provided by Shenzhen Alpha Product Testing Co., is not sufficient to make
15 conclusions about MNGO manufacturing product quality control. I have not worked with Shenzhen
16 Alpha Product Testing Co., Ltd. Therefore, I cannot speak to the quality and standard of this lab. My
17 analysis of their data assumes that the data provided by this lab is correct. Under this assumption,
18 MNGO's specified nicotine target of 53 mg/mL is already approximately 11.7% less than the 60 mg/mL
19 (or 6%) label nicotine concentration. Further, based on its range of 58.3 (+ 10%) - 47.7 (- 10%) mg/mL,
20 MNGO deems a MNGO Stick labeled as containing a 6% nicotine concentration as acceptable at release,
21 even if only contains 47.7 mg/mL, which is 20.5% less than the nicotine concentration advertised on the
22 label. Given the foregoing, not only is MNGO's LOT Release Specification of 53 mg/mL beyond the
23 industry standard of +/-10%, but the lower end of its acceptable range (i.e., 47.7 mg/mL) is twice the
24 industry standard at -20.5%.

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27 5 Flora, J. W., Meruva, N., Huang, C. B., Wilkinson, C. T., Ballantine, R., Smith, D. C., . . . McKinney, W. J. (2016).
28 Characterization of potential impurities and degradation products in electronic cigarette formulations and aerosols. *Regul Toxicol Pharmacol*, 74, 1-11. doi:10.1016/j.yrtph.2015.11.009.

1 17. The MNGO Stick measured nicotine concentrations indicated in the Labstat Report and
2 the Enthalpy Report fall significantly outside the expected ranges typically observed with ENDS. The
3 American E-liquid Manufacturing Standards Association (AEMSA) was formed to certify nicotine
4 concentrations in ENDS products. According to the AEMSA guidelines (posted on the AEMSA Web
5 site as of April 2021; see <https://www.aemsa.org/wp-content/uploads/2017/03/AEMSA-Standards-v2.3.3.pdf>)⁶, nicotine concentrations in ENDS products should be +/-10% of the label.

7 18. Tobacco manufactures express nicotine concentrations in e-liquids in units of weight or
8 volume. Both units are acceptable as long as the product label articulates which units are being used.

9 19. To convert the units of measure from mg/g to mg/mL and vice versa you will need to
10 know the specific gravity of the e-liquid. The specific gravity of an e-liquid depends on the formulation
11 of the e-liquid.

12 20. The measured nicotine data shown in the laboratory tests from Shenzhen Alpha Product
13 Testing Co., Ltd, Labstat International, Inc., Enthalpy Analytical, Inc., and Legend Technical Services,
14 Inc., are all expressed in units of weight (mg/g). Accordingly, there is no difference between any of the
15 labs' data with respect to the nicotine units of measurement. While the report by Labstat International,
16 Inc. does not include a conversion of its data from units of weight (mg/g) to units of volume (mg/mL);
17 the conversion of said data, in my opinion, does not result in a meaningful difference with respect to the
18 overall nicotine concentration in the e-liquid of the MNGO Sticks tested.

19 21. Table 4 shows Labstat's measured nicotine concentration in the MNGO Stick e-liquid in
20 units of weight (mg/g). When the units of weight in this table are shown as percentage values, the nicotine
21 concentration in the various MNGO e-liquids is 3.38%, 3.13% and 3.15%, respectively. When we use
22 the specific gravity of the e-liquid to convert the lab data from units of weight (mg/g) to units of volume
23 (mg/mL), the nicotine concentration of the various MNGO Stick e-liquids is 3.92%, 3.63% and 3.62%,
24 respectively. Accordingly, the conversion calculation makes the numbers slightly larger, but does not
25 change the fact that e-liquid of the MNGO Stick tested by Labstat is less than 4%. The data produced by
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⁶ American e-Liquid Manufacturing Standards Association (AEMSA). (2021). E-Liquid manufacturing standards (Version 2.3.3, pp. 1–10)

1 Enthalpy Analytical, Inc., as shown in Table 5 below, also shows the e-liquid of the MNGO Stick is less
2 than 4% and not 6%, as advertised.

3 22. Enthalpy also measured the liquid volume in the MNGO Sticks. The measured liquid
4 volumes were approximately 26% lower than advertised on the packaging label. The MNGO packaging
5 label suggest that the product contains a total of 84 mg of nicotine with each MNGO product (60 mg/mL
6 x 1.4 mL = 84 mg). However, when you factor in the 26% reduction in e-liquid volume and the 39%
7 decrease in the nicotine liquid concentration, the consumer is only receiving 37.9 mg of nicotine per
8 MNGO Stick. Overall, the consumer is receiving fifty-four percent (54%) less nicotine than indicated
9 on the MNGO Stick label. Fifty-four percent (54%) less nicotine than indicated on the packaging label
10 also is likely to result in the FDA concluding that the proposed labeling is false and misleading.

11 23. Inaccurate information about e-cigarette nicotine concentrations on the packaging could
12 result in more frequent product purchases.

13 24. The amount of nicotine is a leading reason for many vapers to choose their brands of e-
14 cigarettes (after flavor and price).⁷ Additionally, the data from a study conducted in seven countries
15 showed that e-cigarettes with high levels of nicotine provide stronger attenuation of craving for
16 smokers.⁸ A later study by the same author found that experienced vapers trying to quit smoking
17 decreased the nicotine concentration by using refillable e-cigarettes but increased overall consumption
18 of the e-liquids overtime to compensate.⁹ It has also been found that younger non-smokers preferred no
19 nicotine or low nicotine e-cigarettes while smokers preferred medium and high nicotine e-cigarettes.¹⁰
20 These studies support the hypothesis that the consumer will compensate for the lower nicotine
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23 7 Laverty, A. A., Vardavas, C. I., & Filippidis, F. T. (2016). Design and marketing features influencing choice of e-
24 cigarettes and tobacco in the EU. *Eur J Public Health*, 26(5), 838-841. doi:10.1093/eurpub/ckw109

25 8 Etter, J. F. (2015). Explaining the effects of electronic cigarettes on craving for tobacco in recent quitters. *Drug Alcohol
Depend*, 148, 102-108. doi:10.1016/j.drugalcdep.2014.12.030

26 9 Etter, J. F. (2016). A longitudinal study of cotinine in long-term daily users of e-cigarettes. *Drug Alcohol Depend*, 160,
218-221. doi:10.1016/j.drugalcdep.2016.01.003

27 10 Czoli, C. D., Goniewicz, M., Islam, T., Kotnowski, K., & Hammond, D. (2016). Consumer preferences for electronic
28 cigarettes: results from a discrete choice experiment. *Tob Control*, 25(e1), e30-36. doi:10.1136/tobaccocontrol-2015-
052422

1 concentrations and the reduced liquid volume of the MNGO products by increasing their consumption
2 (i.e., buying more MNGO sticks).

3 25. The FDA has indicated that label inaccuracies, including those related to inaccurate
4 nicotine concentrations may result in increased health risks to the consumer.

5 26. Additionally, the rapid nicotine degradation and the chemicals that are formed in the e-
6 liquid of the MNGO Stick may pose an increased health risk to the consumer.

7 27. Lastly, the specific gravity measured and applied by Labstat and Enthalpy in their
8 respective testing (i.e., 1.15 and/or 1.16 g/mL) is greater than the specific gravity applied (not clear if
9 measured) by Alpha (i.e., 1.12 g/mL). Accordingly, if a specific gravity of 1.12 was applied to the data
10 in either the Labstat or Enthalpy reports, the measured nicotine concentration of the tested MNGO Stick
11 e-liquid would be even less, which is already below 4%.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this ____ day of April 2021 at _____, Virginia.

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Willie J. McKinney Ph.D., DABT

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